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SonoSite, Inc. 21919 30th Drive SE Bothell, WA 98021-3904 USA

> Telephone:1.425.951.1200 Facsimile:1.425.951.1201 www.sonosite.com

510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

SonoSite, Inc., 21919 30th Drive SE, Bothell, WA 98021-3904 USA

Corresponding Official:

Christopher J. Hartzog, Sr. Regulatory Affairs Specialist

E-mail:

chris.hartzog@sonosite.com

Telephone:

(425) 951-1419

Facsimile:

(425) 951-1201

Date prepared:

July 1, 2008

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite Maxx™ Series Ultrasound System (subject to change)

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Picture Archiving And Communications System	892.2050	90-LLZ

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the SonoSite Maxx[™] Series Ultrasound System (K071134), the SonoSite MicroMaxx[®] Ultrasound System (K053069 and K043559), the Philips Medical Systems HDI[®] 5000 Ultrasound System (K034003 and K011224) and the GE Logiq 9 Ultrasound System (K061129).

4) Device Description:

The SonoSite Maxx Series Ultrasound System is a full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data in 2D, 2D Chroma, THI, M-Mode, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Power Doppler, Velocity Color Doppler, Anatomical M-Mode, Color M-Mode, Pulsed Wave Tissue Doppler Imaging (PW-TDI), Color Tissue Doppler Imaging (Color-TDI), Elastography (Strain), Strain Rate Imaging, tissue 3D, tissue 4D and flow 3D imaging or in a combination of these modes. The SonoSite Maxx Series is a design that readily lends itself to be configured to specific ultrasound imaging applications through physical packaging adaptations and system feature selections.

5) Indications for Use

The device is intended for prescription use (Per 21 CFR 801.109) for diagnostic ultrasound imaging or fluid flow analysis of the human body in the following clinical applications:

Ophthalmic	Adult Cephalic
Fetal - OB/GYN	Trans-rectal
Abdominal	Trans-vaginal
Intra-operative	
(Abdominal organs and vascular)	Musculo-skel. (Conventional)
Intra-operative (Neuro.)	Musculo-skel. (Superficial)
Laparoscopic	Cardiac Adult
Pediatric	Cardiac Pediatric
Small Organ	
(breast, thyroid, testicles, prostate)	Trans-esophageal (card.)
Neonatal Cephalic	Peripheral vessel

5) Comparison with Predicate Devices

The SonoSite Maxx™ Series Ultrasound System is of a comparable type and substantially equivalent to the current SonoSite Maxx™ Series Ultrasound System. It has the same technological characteristics, safety and effectiveness features, the same physical design and materials. The system has the same intended use and basic operating modes as the SonoSite, Philips HDI5000 and GE Logiq 9 predicate devices.

6) Performance Data

The device is verified and validated according to the company's design control process.

7) Conclusion

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The product development process conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable electromedical device safety standards with compliance verified through independent evaluation and ongoing factory audits. Medical diagnostic ultrasound has an established history of safety and effectiveness. It is the opinion of SonoSite, Inc. that the SonoSite Maxx[™] Series Ultrasound System is substantially equivalent with regard to safety and effectiveness to other devices already cleared for marketing.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

AUG 2 5 2008

SonoSite, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082098

Trade/Device Name: SonoSite MaxxTM Series Ultrasound System (SiteLinkTM Image

Manager and SonoSite® DICOM/Clips Bundle)

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX, and LLZ

Dated: July 24, 2008 Received: July 25, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite MaxxTM Series Ultrasound System (SiteLinkTM Image Manager and SonoSite[®] DICOM/Clips Bundle), as described in your premarket notification:

Transducer Model Number

<u>BPTRTx/8-5</u>	<u>D5x/5</u>	<u>ICTx/8-5</u>
C8x/8-5	C60x/5-2	L25x-13-6
<u>C11x/8-5</u>	HFL38x/13-6	L38x/10-5
D2x/2	HFL50x/15-6	L52x/10-5

LAPx/12-5	TCDx/2	WC40x/6-2
MiniTEEx/7-3	TEEx/8-3	WC60x/6-2
P10x/8-4	<u>L25Bx/10-5</u>	W1.25x/12-5
$\overline{P17x/5-1}$	<u>LFL38x/7-3</u>	$\frac{WL40x/12-5}{L}$
$\overline{P21x/5-1}$	<u>P21Dx/5-1</u>	WMC15x/12-4
SLAx/13-6	P21MCx/5-1	WMC20x/12-4
SLTx/10-5	P21Sx/7-1	<u>WTVx/9-3</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

forum Why

Center for Devices and Radiological Health

Enclosure(s)

Table 4.3- 1 Diagnostic Ultrasound Indications for Use Form – SonoSite Maxx™ Series Ultrasound System

System:	SonoSite	Махх™	Series U	itrasoun	a System						
Transducer:	N/A										
Intended Use:	Diagnostic	c ultraso	und imag	ging or fl	uid flow ar	alysis of the huma	an body as				
Clinical Application	Mode of Operation										
• •					Color	Combined	Other				
	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)				
						B+M; B+PWD;					
Ophthalmic	P	Р	Р		P	B+CD					
			Ì			B+M; B+PWD;					
<u>Fetal</u>	P	Р	Р		Р	B+CD	Note 1				
	_	_	_	_	_	B+M; B+PWD;					
Abdominal	P	Р	Р	P	P	B+CWD; B+CD	Note 1				
Intra-operative (Abdominal			_		_	B+M; B+PWD;					
organs and vascular)	P	P	Р		Р	B+CD	Note 1				
	_	_	_			B+M; B+PWD;					
Intra-operative (Neuro.)	Р	Р	Р	<u> </u>	Р	B+CD	Note 1				
		_	_		_	B+M; B+PWD;					
Laparoscopic	P	P	Р		P	B+CD	Note 1				
	_	_		_	_	B+M; B+PWD;					
Pediatric	P	Р	Р	P	P	B+CWD; B+CD	Note 1				
Small Organ (breast, thyroid,	_	_			_	B+M; B+PWD;					
testicles, prostate)	P	P	Р	ļ	Р	B+CD	Note 1				
	_	_	_			B+M; B+PWD;					
Neonatal Cephalic	P	P	P		Р	B+CD	Note 1				
A L II O L . I'.	_				1 _	B+M; B+PWD;					
Adult Cephalic	P	P	Р	ļ <u>.</u>	Р	B+CD	Note 1				
T					_	B+M; B+PWD;					
Trans-rectal	P	P	Р	ļ	Р	B+CD	Note 1				
Trans vacinal		_				B+M; B+PWD;	N1-4- 4				
Trans-vaginal	P	P	P	 	Р	B+CD	Note 1				
Trans-urethral			ļ	ļ							
Trans-esoph. (non-Card.)		 	 			D.M. D. DIAD					
Museula akal (Convert)	P	_	P			B+M; B+PWD;	Ninta 4				
Musculo-skel. (Convent.)	<u> </u>	P	P	 	Р	B+CD	Note 1				
Musculo-skel. (Superfic.)	P	P	P		D	B+M; B+PWD; B+CD	NI=4= 4				
Intra-luminal	F	 	 	<u> </u>	P	B+CD	Note 1				
	 		-	 		 					
Other (spec.)	-	 	+	1		D.M. D. DUZD.					
Cardiac Adult	Р	P	D		В	B+M; B+PWD; B+CWD: B+CD	Nata 4				
Cardiac Addit	 	- 	P	P	P	B+CVD; B+CD B+M; B+PWD;	Note 1				
Cardiac Pediatric	P	P	P	P	Р	B+CWD; B+CD	Note 1				
Cardiac F Ediatific	 	 		F	F	B+M; B+PWD;	Note 1				
Trans-esophageal (card.)	P	Р	Р	P	P	B+CWD; B+CD	Note 1				
Other (spec.)	 	 		 		DICOVO, BTCD	Note 1				
Outor (Spec.)	 		 	+	+	B+M; B+PWD;					
Peripheral vessel	Р	P	Р		Р	B+IVI; B+PVVD;	Note 1				
Other (spec.)	 	- -'	+		<u> </u>	5,00	NOG I				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, and imaging for guidance of biopsy. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Includes imaging of spinal cord to provide guidance for central nerve block procedures. Includes jucture archiving, communications and storage functionality. Mode includes anatomical M-Mode, and color M-Mode. System includes wireless voice activited remote control capabilities. System includes the ability to perform

Mode includes anatomical M-Mode, and color M-Mode. System includes wi	central relive block procedures. Includes picture archiving, continuincations and storage functionality. reless voice activ∦ted remote control capabilities. System includes the ability to perform
measurements on recalled images.	In a mother
	Mad IN TIME
All items marked "P" were previously cleared in 510(k) K071134.	(Division/Sign_Off)
	(Division sign-on)
Prescription Use (Per 21 CFR 801.109)	Division of Reproductive, Abdominal and
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Indications for Use Section 4.3

INDICATIONS FOR USE

510(k) Number (if known):	K 0	J26	7)0	
Device Name: <u>SiteLink[™] Ima</u> g	ie Mana	ager-		
Maxx Series medical diagnostic	c ultras	ound s	nager is a software accessory for systems. SiteLink enables image of ed .jpg format, from SonoSite sys	download,
Prescription Use:	\checkmark	or	Over-The-Counter Use:	
(Part 21 CFR 801 Subpart D)			(Part 21 CFR 807 Subpart C)	
(PLEASE DO NOT WRITE BELOW	THIS LIN	E-CON	TINUE ON ANOTHER PAGE OF NEEDE	≘D)
Concurrence of	CDRH,	, Offic	e of Device Evaluation (ODE)	

(Optional Format 3-10-98)

(Division Sign-Off)
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INDICATIONS FOR USE

510(k) Number (if known): < ○ ∂ 2 0 9 8
Device Name: SonoSite® DICOM/Clips Bundle-
Indications for Use: The SonoSite® DICOM/Clips Bundle is a software option available on SonoSite Maxx Series TM medical diagnostic ultrasound systems. It is intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation.
Prescription Use:
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)
(Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number

Table 4.3- 2 Diagnostic Ultrasound Indications for Use Form – BPTRTx/8-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System												
Transducer:	BPTF	RTx/8-5	MHz Transo	lucer									
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:												
Clinical Application	Mode of Operation												
• • • • • • • • • • • • • • • • • • • •	вм		PWD	CWD	Color Doppier	Combined (Spec.)	Other (Spec.)						
Ophthalmic													
Fetal	Р	Р	P		P	B+M; B+PWD; B+CD	Note 1						
Abdominal													
Intra-operative (Abdominal organs and vascular)													
Intra-operative (Neuro.)													
Laparoscopic													
Pediatric													
Small Organ (breast, thyroid, testicles, prostate)	Р	P	Ρ		Р	B+M; B+PWD; B+CD	Note 1						
Neonatal Cephalic													
Adult Cephalic		ļ											
Trans-rectal	Р	Р	P		Р	B+M; B+PWD; B+CD	Note 1						
Trans-vaginal	P	Р	Р		Р	B+M; B+PWD; B+CD	Note 1						
Trans-urethral					<u> </u>								
Trans-esoph. (non-Card.)													
Musculo-skel. (Convent.)							ļ						
Musculo-skel. (Superfic.)													
Intra-luminal													
Other (spec.)													
Cardiac Adult													
Cardiac Pediatric													
Trans-esophageal (card.)													
Other (spec.)													
Peripheral vessel													
Other (spec.)													

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography Imaging, strain rate Imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 3 Diagnostic Ultrasound Indications for Use Form – C8x/8-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System									
Transducer:	C8	x/8-5	MHz Ti	ransduc	er					
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the									
Mitoriada ess.						•				
Clinical Application	human body as follows: Mode of Operation									
Cillical Application		ſ · · · · · ·		1110	Color	Combined	Other			
	В	м	PWD	CWD	Doppler	(Spec.)	(Spec.)			
Ophthalmic		141	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	0112	В орриот	(0)00.7	1 (0,000.)			
Органалне			l			B+M; B+PWD;				
Fetal	Р	Р	P		P	B+CD	Note 1			
Abdominal										
Intra-operative (Abdominal organs and vascular)										
Intra-operative (Neuro.)										
Laparoscopic										
Pediatric										
Small Organ (breast, thyroid, testicles, prostate)	T									
Neonatal Cephalic										
Adult Cephalic										
						B+M; B+PWD;				
Trans-rectal	P	Р	P		P	B+CD	Note 1			
					i l	B+M; B+PWD;				
Trans-vaginal	P	P	P		Р	B+CD	Note 1			
Trans-urethral			<u> </u>							
Trans-esoph. (non-Card.)		<u> </u>								
Musculo-skel. (Convent.)		<u> </u>								
Musculo-skel. (Superfic.)										
Intra-luminal			1	1						
Other (spec.)		<u> </u>								
Cardiac Adult	<u> </u>		ļ	ļ <u>.</u>						
Cardiac Pediatric		<u> </u>	1	<u> </u>						
Trans-esophageal (card.)	↓	1		ļ <u>.</u>						
Other (spec.)										
Peripheral vessel										
Other (spec.)				l						

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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(k) Number KUSZU 10

Indications for Use Section 4.3

Table 4.3- 4 Diagnostic Ultrasound Indications for Use Form - C11x/8-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System C11x/8-5 MHz Transducer								
Transducer:									
Intended Use:	Dia	agno	stic ultr	asound	imaging o	r fluid flow analysis of	the		
,						•			
Clinical Application	human body as follows: Mode of Operation								
Cillical Application				TT	Color	Combined	Other		
	В	м	PWD	CWD	Doppler	(Spec.)	(Spec.)		
Ophthalmic	-5	tAI	1 440	OVVD	Воррісі	(Орсс.)	(Opco.)		
Fetal	 								
i etai	 					B+M: B+PWD:			
Abdominal	Р	Р	P	P	P	B+CWD; B+CD	Note 1		
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1		
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1		
Laparoscopic	Ė	i i			1				
<u> </u>						B+M; B+PWD;			
Pediatric	Р	Р	Р	Р	ļР	B+CWD: B+CD	Note 1		
Small Organ (breast, thyroid, testicles, prostate)	1					-			
Neonatal Cephalic	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1		
***	1								
Adult Cephalic		ļ	ļ						
Trans-rectal									
Trans-vaginal						1.41-2.41-2.11			
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Convent.)									
Musculo-skel. (Superfic.)				T					
Intra-luminal									
Other (spec.)	1						}		
Cardiac Adult									
	}					B+M; B+PWD;			
Cardiac Pediatric	P	P	I P	Р	P	B+CWD; B+CD	Note 1		
Trans-esophageal (card.)	<u> </u>						<u> </u>		
Other (spec.)	$oxed{oxed}$		ļ	<u> </u>					
Peripheral vessel	P	Р	P		P	B+M; B+PWD; B+CD	Note 1		
Other (spec.)	<u></u>	<u></u>	1		1				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography Imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number __

Table 4.3- 5 Diagnostic Ultrasound Indications for Use Form - D2x/2 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	D2x/2 MHz Dual Element Circular Array						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						of the
Clinical Application				Mode	of Opera		
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic						ļ	
Fetal		<u> </u>				ļ 	ļ
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)		<u> </u>				ļ	!
Laparoscopic	<u> </u>						ļ
Pediatric					.,	<u></u>	
Small Organ (breast, thyroid, testicles, prostate)				<u> </u>			
Neonatal Cephalic		<u> </u>					
Adult Cephalic		<u> </u>				<u> </u>	
Trans-rectal						 	
Trans-vaginal			<u> </u>	ļ			
Trans-urethral							
Trans-esoph. (non-Card.)				ļ		<u> </u>	
Musculo-skel. (Convent.)		<u></u>		<u> </u>			
Musculo-skel. (Superfic.)		<u> </u>					\
Intra-luminal				ļ <u>.</u>			<u> </u>
Other (spec.)		<u> </u>					
Cardiac Adult				PP			
Cardiac Pediatric	<u> </u>		1	Р	1		1
Trans-esophageal (card.)					ļ	<u> </u>	_
Other (spec.)		1	_	<u> </u>			
Peripheral vessel							
Other (spec.)			<u> </u>	1	1	<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
ision of Reproductive, Abdominal and

adiological Devices

510(k) Number .

Section 4.3

Table 4.3- 6 Diagnostic Ultrasound Indications for Use Form – D5x/5 Transducer

System:	Sor	SonoSite Maxx™ Series Ultrasound System							
Transducer:	D5x	D5x/5 MHz Dual Element Circular Array							
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application	Mode of Operation								
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)		
Ophthalmic		[· · · · · · · · · · · · · · · · · · ·			
Fetal									
Abdominal						<u> </u>			
Intra-operative (Abdominal organs and vascular)	<u> </u>	<u> </u>				-			
Intra-operative (Neuro.)									
Laparoscopic	<u> </u>								
Pediatric		<u> </u>					<u> </u>		
Small Organ (breast, thyroid, testicles, prostate)				ļ			 -		
Neonatal Cephalic		<u> </u>		<u> </u>					
Adult Cephalic	<u>l</u>			<u> </u>	ļ		ļ		
Trans-rectal					<u> </u>				
Trans-vaginal	<u> </u>			<u> </u>	-		ļ		
Trans-urethral				ļ					
Trans-esoph. (non-Card.)		<u> </u>							
Musculo-skel. (Convent.)						ļ	<u> </u>		
Musculo-skel. (Superfic.)		1			<u> </u>		ļ.——		
Intra-luminal		<u> </u>							
Other (spec.)			<u> </u>						
Cardiac Adult				P		<u> </u>			
Cardiac Pediatric		_		Р	ļ	-	<u> </u>		
Trans-esophageal (card.)					ļ		 		
Other (spec.)		1	ļ	<u> </u>			-		
Peripheral vessel		<u> </u>							
Other (spec.)	<u> </u>		1	<u> </u>	1		1		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Section 4.3

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Table 4.3- 7 Diagnostic Ultrasound Indications for Use Form - C60x/5-2 Transducer

System:	So	noSit	е Махх	™ Serie	s Ultrasoun	d System	
Transducer:	C6	0x/5-	2 MHz	Transdu	cer		
Intended Use:				sound ir follows:		uid flow analysis o	of the
Clinical Application					de of Ope	ration	
••	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic			1,110	0.00	Боррісі	(орос.)	(Speci.)
Fetal	Р	Р	P		Р	B+M; B+PWD; B+CD	Note 1
Abdominal	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							<u> </u>
Laparoscopic					1		<u> </u>
Pediatric	P	Р	Р		Р	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal						<u>'</u>	
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)		1	1				
Other (spec.)					1		
Peripheral vessel	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1
Other (spec.)					1		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 8 Diagnostic Ultrasound Indications for Use Form - HFL38x/13-6 Transducer

System:	Soi	SonoSite Maxx™ Series Ultrasound System										
Transducer:	HF	L38x	/13-6 M	Hz Tran	sducer							
Intended Use:				sound ir		uid flow analysis o	of the					
Clinical Application	Mode of Operation											
••	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic												
Fetal							1					
Abdominal	Р	Р	P		Р	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Neuro.)					1		1					
Laparoscopic							ļ					
Pediatric	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1					
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal							•					
Trans-vaginal	<u> </u>			i		·						
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skel (Convent.)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Musculo-skel. (Superfic.)	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1					
Intra-luminal	ļ											
Other (spec.)												
Cardiac Adult												
Cardiac Pediatric												
Trans-esophageal (card.)												
Other (spec.)		1]									
Peripheral vessel	P	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Other (spec.)	T	† <u> </u>	†	<u> </u>		<u> </u>	1					

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode.

M-Mode Includes anatomical M-Mode, and color M-Mode.

All Items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 9 Diagnostic Ultrasound Indications for Use Form - HFL50x/15-6 Transducer

System:	So	SonoSite Maxx™ Series Ultrasound System										
Transducer:	HF	L50>	√15-6 M	Hz Tran	sducer							
Intended Use:	Dia	igno	stic ultra	sound in	maging or f	uid flow analysis	of the					
			body as			,						
Clinical Application	Mode of Operation											
• •	-				Color	Combined	Other					
	В	М	PWD	CWD	Doppler	(Spec.)	(Spec.)					
Ophthalmic												
Fetal												
Abdominal	Р	P	Р		P	B+M; B+PWD; B+CD	Note 1					
				,		B+M; B+PWD;						
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+CD	Note 1					
Intra-operative (Neuro.)												
Laparoscopic				4.11								
Pediatric	Р	P	Р		Р	B+M; B+PWD; B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Neonatal Cephalic							11010					
Adult Cephalic				-								
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)		T					<u> </u>					
Musculo-skel. (Convent.)	Р	Р	Р	-	Р	B+M; B+PWD; B+CD	Note 1					
Musculo-skel. (Superfic.)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Intra-luminal					; · · · · · · · · · · · · · · · · · · ·	<u> </u>	1.10.0					
Other (spec.)												
Cardiac Adult	[1					
Cardiac Pediatric												
Trans-esophageal (card.)	L											
Other (spec.)							 					
Peripheral vessel	P	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Other (spec.) N= new indication; P= previously cleared by FDA; E= ac					-		1,1000					

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography Imaging, strain rate Imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 10 Diagnostic Ultrasound Indications for Use Form – ICTx/8-5 Transducer

System:	So	SonoSite Maxx™ Series Ultrasound System									
Transducer:				ransduc							
Intended Use:	Dia	anos	stic ultra	sound in	naging or f	luid flow analysis	of the				
				follows:		idid ilott dilaijoio	01 (110				
Clinical Application	11.01	High	bouy as			4!					
Clinical Application	<u> </u>			eration	, ,						
		١		0145	Color	Combined	Other				
	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)				
Ophthalmic											
Estal						B+M; B+PWD;	l				
Fetal Abdominal	Р	P	Р		Р	B+CD	Note 1				
	ļ		<u> </u>				ļ				
Intra-operative (Abdominal organs and vascular)	-	ļ									
Intra-operative (Neuro.)	-						<u> </u>				
Laparoscopic Pediatric	 	-			<u> </u>		1				
			<u> </u>								
Small Organ (breast, thyroid, testicles, prostate)		├	<u> </u>								
Neonatal Cephalic	 	 			ļ. <u>-</u>						
Adult Cephalic	 	├				D 14 D D14D					
Trans-rectal	Р	P			_]	B+M; B+PWD;	N1-4-4				
Trans-lectar	+-		P		P	B+CD	Note 1				
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	No.				
Trans-vaginar	╀╴	F	<u> </u>		P	B+CD	Note 1				
Trans-esoph. (non-Card.)	+-	 		-							
Musculo-skel. (Convent.)	+	-	-	 			_				
Musculo-skel. (Superfic.)	+	1	-								
Intra-luminal	+	 					 				
Other (spec.)	+	 	 								
Cardiac Adult	+										
Cardiac Pediatric	+	 	+								
Trans-esophageal (card.)	+	 	 	-	 						
Other (spec.)	+	 	-	 							
Peripheral vessel	 	 	ļ <u></u>	 			+				
Other (spec.)	+	+									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 11 Diagnostic Ultrasound Indications for Use Form – L25x/13-6 Transducer

System:	So	SonoSite Maxx™ Series Ultrasound System										
Transducer:	L25	5x/13	3-6 MHz	Transdo	ıcer							
Intended Use:	Dia	anos	stic ultra	sound ir	naging or fl	uid flow analysis	of the					
				follows:		,,						
Clinical Application	Mode of Operation											
		T			Color	Combined	Other					
	В	М	PWD	CWD	Doppler	(Spec.)	(Spec.)					
Ophthalmic	N	N			N	B+M; B+CD	Note 1					
Fetal												
Abdominal	Р	P			Р	B+M; B+CD	Note 1					
Intra-operative (Abdominal organs and												
vascular)	P	P			P	B+M; B+CD	Note 1					
Intra-operative (Neuro.)												
Laparoscopic												
						B+M; B+CWD;						
Pediatric	P	P			P	B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; B+CD	Note 1					
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal	1						I					
Trans-urethral	<u> </u>						l					
Trans-esoph. (non-Card.)					<u> </u>							
Musculo-skel. (Convent.)	P	Р			P	B+M; B+CD	Note 1					
Musculo-skel. (Superfic.)	P	P			Р	B+M; ;B+CD	Note 1					
Intra-luminal												
Other (spec.)		<u> </u>										
Cardiac Adult												
Cardiac Pediatric	<u> </u>											
Trans-esophageal (card.)												
Other (spec.)												
Peripheral vessel	Р	Р			Р	B+M; B+CD	Note 1					
Other (spec.)												

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate Imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 12 Diagnostic Ultrasound Indications for Use Form - L38x/10-5 Transducer

System:	So	noSi	te Maxx	™ Serie	s Ultrasoun	d System						
Transducer:				Transdo								
Intended Use:	Dia	gno	stic ultra		maging or fl	uid flow analysis	of the					
Clinical Application	Mode of Operation											
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic	-						1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					
Fetal				**********		• • • • • • • • • • • • • • • • • • • •						
Abdominal	P	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Neuro.)												
Laparoscopic												
Pediatric	P	Р	P		Р	B+M; B+PWD; B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	Р	P	P		Р	B+M; B+PWD; B+CD	Note 1					
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skel. (Convent.)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Musculo-skel. (Superfic.)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Intra-luminal	1											
Other (spec.)	<u> </u>	<u> </u>										
Cardiac Adult	<u> </u>	Ļ										
Cardiac Pediatric												
Trans-esophageal (card.)												
Other (spec.)	<u> </u>											
Peripheral vessel	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Other (spec.)												

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 13 Diagnostic Ultrasound Indications for Use Form – L52x/10-5 Transducer

System:	So	noSi	te Maxx	™ Serie	s Ultrasour	nd System	
Transducer:				Transdu			
Intended Use:				sound ir		luid flow analysis	of the
Clinical Application				Мо	de of Ope	eration	
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic		-					
Fetal	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1
Abdominal	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic		<u> </u>					
Pediatric	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic				ļ <u></u> .			
Trans-rectal				<u></u>			
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)			<u> </u>				
Musculo-skel. (Convent.)	Р	P	Р		Р	B+M; B+PWD; B+CD	Note 1
Muscuto-skel. (Superfic.)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)	<u> </u>	ļ					
Peripheral vessel	Р	P	P		Р	B+M; B+PWD; B+CD	Note 1
Other (spec.)							1

N= new Indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

Table 4.3- 14 Diagnostic Ultrasound Indications for Use Form – LAPx/12-5 Laparoscopic Transducer

System:		SonoSite Maxx™ Series Ultrasound System										
Transducer:	LA	Px/1:	2-5 MHz	Transd	ucer							
Intended Use:	Dia	gnos	stic ultra		naging or fl	uid flow analysis	of the					
Clinical Application	Mode of Operation											
- постана при постана	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic												
Fetal												
Abdominal				<u> </u>								
Intra-operative (Abdominal organs and vascular)							1					
Intra-operative (Neuro.)		 					1					
		·			1	B+M; B+PWD;						
Laparoscopic	Р	Р	P		P	B+CD	Note 1					
Pediatric												
Small Organ (breast, thyroid, testicles, prostate)												
Neonatal Cephalic		[
Adult Cephalic						_						
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)		T										
Musculo-skel. (Convent.)	Ĭ						_					
Musculo-skel. (Superfic.)												
Intra-luminal					_							
Other (spec.)												
Cardiac Adult							_					
Cardiac Pediatric												
Trans-esophageal (card.)												
Other (spec.)												
Peripheral vessel	L_											
Other (spec.)												

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography Imaging, strain rate Imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 15 Diagnostic Ultrasound Indications for Use Form – MiniTEEx/7-3 Transducer

System:	SonoSite Maxx™ Series Ultrasound System										
Transducer:					z Transd						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application	Mode of Operation										
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)				
Ophthalmic	Ī					(0,000.)	(0000.)				
Fetal	1	<u> </u>									
Abdominal		<u> </u>									
Intra-operative (Abdominal organs and vascular)											
Intra-operative (Neuro.)											
Laparoscopic	T		·								
Pediatric											
Small Organ (breast, thyroid, testicles, prostate)											
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal	Γ										
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Convent.)											
Musculo-skel. (Superfic.)											
Intra-luminal											
Other (spec.)		ŀ									
Cardiac Adult											
Cardiac Pediatric											
Trans-esophageal (card.)	Р	Р	Р	Р	P	B+M; B+PWD; B+CWD; B+CD	Note 1				
Other (spec.)											
Peripheral vessel											
Other (spec.)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography Imaging, strain rate Imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 16 Diagnostic Ultrasound Indications for Use Form – P10x/8-4 Transducer

System:	SonoSite Maxx™ Series Ultrasound System										
Transducer:					ansducer						
Intended Use:	D	iag	nostic		und imag	ging or fluid flow analysis of t	he				
Clinical Application	Mode of Operation										
	В	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)				
Ophthalmic	Р	Ρ	P		P	B+M; B+PWD; B+CD	Note 1				
Fetal	Р	Р	_P		Р	B+M; B+PWD B+CD	Note 1				
Abdominal	Р	Ъ	P	P	Р	B+M; B+PWD; B+CWD; B+CD	Note 1				
Intra-operative (Abdominal organs and vascular)	-	_	P		P	B+M; B+PWD B+CD	Note 1				
Intra-operative (Neuro.)	Ρ	Р	P		Р	B+M; B+PWD; B+CD	Note 1				
Laparoscopic	L										
Pediatric	Р	Ъ	Р		Р	B+M; B+PWD	Note 1				
Small Organ (breast, thyroid, testicles, prostate)	Р	P	Р		Р	B+M; B+PWD B+CD	Note 1				
Neonatal Cephalic	Р	Р	Р		P	B+M; B+PWD B+CD	Note 1				
Adult Cephalic	Ρ	Р	Р		Р	B+M; B+PWD; B+CD	Note 1				
Trans-rectal	L										
Trans-vaginal	L	Ш									
Trans-urethral	L	Щ									
Trans-esoph. (non-Card.)											
Musculo-skel. (Convent.)	Ρ	Р	Р		Р	B+M; B+PWD B+CD	Note 1				
Musculo-skel. (Superfic.)		Ш									
Intra-luminal	L										
Other (spec.)	L	Ш									
Cardiac Adult	Р	Р	Р	Р	Р	B+M; B+PWD; B+CWD; B+CD	Note 1				
Cardiac Pediatric	Ρ	Р	P	Р	Ρ	B+M; B+PWD; B+CWD; B+CD	Note 1				
Trans-esophageal (card.)	L	\sqcup									
Other (spec.)	L	Ш									
Peripheral vessel	Ρ	Р	Р		Р	B+M; B+PWD; B+CD	Note 1				
Other (spec.)		L									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes cofor power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography Imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

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Table 4.3- 17 Diagnostic Ultrasound Indications for Use Form – P17x/5-1 Transducer

System:	SonoSite Maxx™ Series Ultrasound System											
Transducer:	P17x/5-1 MHz Transducer											
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:											
Clinical Application		Mode of Operation										
		М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic	P	J	Р		Р	B+M; B+PWD; B+CD	Note 1					
Fetal	Р	Р	Р		₽	B+M; B+PWD B+CD	Note 1					
Abdominal	Р	Ρ	Р	Р	Р	B+M; B+PWD; B+CWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)	Р	Р	P.		Р	B+M; B+PWD B+CD	Note 1					
Intra-operative (Neuro.)												
Laparoscopic												
Pediatric	Ρ	Р	P		Р	B+M; B+PWD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	Р	Р	Р		P	B+M; B+PWD B+CD	Note 1					
Neonatal Cephalic	Р		P		P	B+M; B+PWD B+CD	Note 1					
Adult Cephalic	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1					
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)		<u> </u>										
Musculo-skel. (Convent.)	Р	Р	P		P	B+M; B+PWD B+CD	Note 1					
Musculo-skel. (Superfic.)												
Intra-luminal												
Other (spec.)					·							
Cardiac Adult	Р	Ρ	P	Р	Р	B+M; B+PWD; B+CWD; B+CD	Note 1					
Cardiac Pediatric	Р	Ρ	P	Р	Р	B+M; B+PWD; B+CWD; B+CD	Note 1					
Trans-esophageal (card.)												
Other (spec.)												
Peripheral vessel	P	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Other (spec.)	Γ											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography Imaging, strain rate Imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode Includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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Table 4.3- 18 Diagnostic Ultrasound Indications for Use Form – P21x/5-1 Transducer

System:	SonoSite Maxx™ Series Ultrasound System								
Transducer:	P	21x	/5-1 N	iHz Tra	ansducer				
Intended Use:				ultraso ly as fo		jing or fluid flow analysis of the	ne		
Clinical Application	Mode of Operation								
		М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)		
Ophthalmic	Р	Р	P		Р	B+M; B+PWD; B+CD	Note 1		
Fetal	Р	Р	Р		P	B+M; B+PWD B+CD	Note 1		
Abdominal	Р	Р	P	P	Ρ	B+M; B+PWD; B+CWD; B+CD	Note 1		
Intra-operative (Abdominal organs and vascular)	Р	Р	Р		P	B+M; B+PWD B+CD	Note 1		
Intra-operative (Neuro.)	L								
Laparoscopic									
Pediatric	P	Р	Р		Р	B+M; B+PWD	Note 1		
Small Organ (breast, thyroid, testicles, prostate)	P	P	Р		P	B+M; B+PWD B+CD	Note 1		
Neonatal Cephalic	Р		P		Р	B+M; B+PWD B+CD	Note 1		
Adult Cephalic	Р	P	Р		Р	B+M; B+PWD; B+CD	Note 1		
Trans-rectal		<u> </u>							
Trans-vaginal	L	<u> </u>							
Trans-urethral	╙			<u> </u>					
Trans-esoph. (non-Card.)	L								
Musculo-skel. (Convent.)	P	Р	Р		Р	B+M; B+PWD B+CD	Note 1		
Musculo-skel. (Superfic.)		L							
Intra-luminal]		<u> </u>	<u> </u>				
Other (spec.)									
Cardiac Adult	Р	_	Р	P	Р	B+M; B+PWD; B+CWD; B+CD	Note 1		
Cardiac Pediatric	P	P	Р	Р	P	B+M; B+PWD; B+CWD; B+CD	Note 1		
Trans-esophageal (card.)									
Other (spec.)									
Peripheral vessel	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1		
Other (spec.)	Γ								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography Imaging, strain rate Imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode Includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 19 Diagnostic Ultrasound Indications for Use Form – SLAx/13-6 Transducer

System:	So	SonoSite Maxx™ Series Ultrasound System							
Transducer:		SLAx/13-6 MHz Transducer							
Intended Use:	Dia	ignos	stic ultra		maging or f	luid flow analysis	of the		
Clinical Application			· · · · · ·		de of Ope	ration			
	В	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)		
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1		
Fetal	ļ								
Abdominal									
Intra-operative (Abdominal organs and vascular)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1		
Intra-operative (Neuro.)	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1		
Laparoscopic	ļ								
Pediatric	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1		
Small Organ (breast, thyroid, testicles, prostate)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1		
Neonatal Cephalic		<u> </u>							
Adult Cephalic									
Trans-rectal							_ [
Trans-vaginal	ļ								
Trans-urethral									
Trans-esoph. (non-Card.)						B+M; B+PWD;			
Musculo-skel. (Convent.)	Р	Р	Р		P	B+CD	Note 1		
Musculo-skel. (Superfic.)	Р	Р	P		Р	B+M; B+PWD; B+CD	Note 1		
Intra-luminal									
Other (spec.)							 		
Cardiac Adult									
Cardiac Pediatric							<u> </u>		
Trans-esophageal (card.)									
Other (spec.)									
Peripheral vessel	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1		
Other (spec.)							1		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging. SonoMB compound imaging, tissue Doppler imaging (TDI), etastography imaging, strain rate imaging, liastic namenic imaging, sonorces control imaging, strain rate imaging, liastic namenic imaging, sonorces control imaging, sonor

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 20 Diagnostic Ultrasound Indications for Use Form – SLTx/10-5 Transducer

System:	So	noSi	te Maxx	™ Serie	s Ultrasour	nd System						
Transducer:	SL	Tx/1	0-5 MHz	Transd	ucer							
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:											
Clinical Application					de of Ope	ration						
	В	м	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic				· · · · · · · · · · · · · · · · · · ·		(350.7)	1-10000.)					
Fetal	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Abdominal	Р	Р	Р		P	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)	Р	Р	P		P	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Neuro.)	_											
Laparoscopic Pediatric	Р	Р	P		Р	B+M; B+PWD; B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Neonatal Cephalic												
Adult Cephalic				<u> </u>								
Trans-rectal												
Trans-vaginal				<u></u>								
Trans-urethral				<u> </u>								
Trans-esoph. (non-Card.) Musculo-skel. (Convent.)	P	P	Р	<u></u>	P	B+M; B+PWD; B+CD	Note 1					
Musculo-skel. (Superfic.)	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Intra-luminal												
Other (spec.)												
Cardiac Adult												
Cardiac Pediatric	ļ											
Trans-esophageal (card.)	ļ											
Other (spec.)	ļ <u>.</u>											
Peripheral vessel	Р	Р	Р		Р	B+M; B+PWD; B+CD	Note 1					
Other (spec.) N= new indication: P= previously cleared by FDA: E= ag												

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 21 Diagnostic Ultrasound Indications for Use Form – TCDx/2 Transducer

System:	SonoSite Maxx™ Series Ultrasound System									
Transducer:				ransduce						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application	Mode of Operation									
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)			
Ophthalmic			Р			. ((0)00./			
Fetal							 			
Abdominal							<u> </u>			
Intra-operative (Abdominal organs and vascular)			-				 			
Intra-operative (Neuro.)										
Laparoscopic						······································	 			
Pediatric							<u> </u>			
Small Organ (breast, thyroid, testicles, prostate)										
Neonatal Cephalic										
Adult Cephalic			N							
Trans-rectal										
Trans-vaginal			-							
Trans-urethral							T			
Trans-esoph. (non-Card.)			_							
Musculo-skel. (Convent.)										
Musculo-skel. (Superfic.)										
Intra-luminal										
Other (spec.)										
Cardiac Adult										
Cardiac Pediatric			-							
Trans-esophageal (card.)										
Other (spec.)										
Peripheral vessel										
Other (spec.) N= new indication; P= previously cleared by FDA: E= a										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

All Items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 22 Diagnostic Ultrasound Indications for Use Form - TEEx/8-3 Transducer

System:	SonoSite Maxx™ Series Ultrasound System							
Transducer:	T	EE	x/8-3 N	/Hz Tr	ansducei	-		
Intended Use:	D	iag	nostic		und imag	ging or fluid flow analysis of t	he	
Clinical Application					Mode	of Operation		
	В	м	PWD	CWD	Color Doppler	Combined (Spec.)	Other	
Ophthalmic	Ī			3.12	Doppici	(Spec.)	(Spec.)	
Fetal								
Abdominal	T							
Intra-operative (Abdominal organs and vascular)	T							
Intra-operative (Neuro.)	1							
Laparoscopic								
Pediatric	Г							
Small Organ (breast, thyroid, testicles, prostate)								
Neonatal Cephalic			-					
Adult Cephalic	Γ							
Trans-rectal								
Trans-vaginal								
Trans-urethral	Г							
Trans-esoph. (non-Card.)	Γ							
Musculo-skel. (Convent.)								
Musculo-skel. (Superfic.)								
Intra-luminal	Г							
Other (spec.)								
Cardiac Adult	Γ.							
Cardiac Pediatric								
Trans-esophageal (card.)	Р	Р	Р	Р	P	B+M; B+PWD; B+CWD; B+CD	Note 1	
Other (spec.)					-	=, 5.1.1.0, 5.01,6, B10B	NOTO	
Peripheral vessel								
Other (spec.) N= new indication; P= previously cleared by FDA: E= a								

= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 23 Diagnostic Ultrasound Indications for Use Form – L25Bx/10-5 Transducer

System:	SonoSite	SonoSite Maxx™ Series Ultrasound System										
Transducer:	L25Bx/10	-5 MHz	Transduc	er		124 112 112						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human bo follows:										
Clinical Application	Mode of Operation											
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic	N	N	Ņ		N	B+M; B+PWD; B+CD	Note 1					
Fetal			ļ <u>.</u>			2.14.2						
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)												
Intra-operative (Neuro.)												
Laparoscopic												
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
			1			B+M; B+PWD;	11016 1					
Neonatal Cephalic_	N	N	N		N	B+CD	Note 1					
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skel. (Convent.)					1							
Musculo-skel. (Superfic.)												
Intra-luminal												
Other (spec.)												
Cardiac Adult							· · · · · · · · · · · · · · · · · · ·					
Cardiac Pediatric												
Trans-esophageal (card.)												
Other (spec.)												
Peripheral vessel	N	N			N	B+M; B+PWD; B+CD	Note 1					
Other (spec.)		``\``` ```					11010					

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 24 Diagnostic Ultrasound Indications for Use Form – LFL38x/7-3 Transducer

System:	SonoSite	SonoSite Maxx™ Series Ultrasound System										
Transducer:	LFL38x/7-	3 MHz	Transduc	er								
Intended Use:	Diagnostic follows:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application	Mode of Operation											
••	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal	1	1	-									
organs and vascular)												
Intra-operative (Neuro.)							.,					
Laparoscopic												
Pediatric												
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Neonatal Cephalic	1											
Adult Cephalic	1											
Trans-rectal	1											
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)		<u> </u>	<u> </u>									
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Musculo-skel. (Superfic.)												
Intra-luminal												
Other (spec.)												
Cardiac Adult												
Cardiac Pediatric												
Trans-esophageal (card.)												
Other (spec.)												
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Other (spec.)		1	 	 	1							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Indications for Use

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Table 4.3- 25 Diagnostic Ultrasound Indications for Use Form – P21Dx/5-1 Transducer

System:	SonoSite	Maxx™	Series L	lltrasoun	d System	-	
Transducer:	P21Dx/5-	1 MHz T	ransduce	er			
Intended Use:	Diagnosti follows:	c ultraso	und ima	ging or fl	uid flow ar	nalysis of the huma	an body as
Clinical Application				Mode o	of Operat	ion	
	В	м	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal	N	N	N		N	B+M; B+PWD B+CD	Note 1
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD B+CD	Note 1
Intra-operative (Neuro.) Laparoscopic	-			<u> </u>			
Pediatric	N	N	N	 	N	B+M; B+PWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD B+CD	Note 1
Neonatal Cephalic	N	N	N		N	B+M; B+PWD B+CD	Note 1
Adult Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral		<u> </u>					
Trans-esoph. (non-Card.) Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal Other (spec.)			 	ļ			
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.) Other (spec.)			1				
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)			1	1	†	† · · · · · · · · · · · · · · · · · · ·	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 26 Diagnostic Ultrasound Indications for Use Form - P21MCx/5-1 Transducer

System:	SonoSite	Махх [™]	Series U	Iltrasoun	d System							
Transducer:	P21MCx/	5-1 MHz	Transdu	cer								
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body follows:											
Clinical Application	Mode of Operation											
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic					1 ''-		<u> </u>					
Fetal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1					
Abdominal	N N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)							· · · · · · · · · · · · · · · · · · ·					
Intra-operative (Neuro.)												
Laparoscopic												
Pediatric					****							
Small Organ (breast, thyroid, testicles, prostate)				-								
Neonatal Cephalic					···							
Adult Cephalic	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1					
Trans-rectal		-			<u> </u>	J - 0.1.B, D - 0.5	110101					
Trans-vaginal												
Trans-urethral			†		<u> </u>							
Trans-esoph. (non-Card.)		1	 									
Musculo-skel. (Convent.)		1	†									
Musculo-skel. (Superfic.)		 	 									
Intra-luminal												
Other (spec.)			† · · · · · · ·		l							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 4					
Cardiac Pediatric		 	 	1,1		B.CAAD, B.CD	Note 1					
Trans-esophageal (card.)		1	<u> </u>		 							
Other (spec.)		1	 									
Peripheral vessel			 				·····					
Other (spec.)	 	 	 									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 27 Diagnostic Ultrasound Indications for Use Form – P21Sx/7-1 Transducer

System:	SonoSite	SonoSite Maxx™ Series Ultrasound System										
Transducer:	P21Sx/7-	1 MHz T	ransduce	er	, 5.0/11							
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body follows:											
Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic				1	2000.00	(Opec.)	(Spec.)					
Fetal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1					
Abdominal	N	N	N	l N	N	B+M; B+PWD; B+CWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)			"				11016					
Intra-operative (Neuro.)												
Laparoscopic					-							
Pediatric						 						
Small Organ (breast, thyroid, testicles, prostate)			-									
Neonatal Cephalic		-										
Adult Cephalic	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1					
Trans-rectal				<u></u>		B. 0415, B. 05	14016 1					
Trans-vaginal			 -									
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skei. (Convent.)												
Musculo-skel. (Superfic.)			<u> </u>									
Intra-luminal		 	 									
Other (spec.)												
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 4					
Cardiac Pediatric		 	· · · · ·	14	14	DIOVID, BTOD	Note 1					
Trans-esophageal (card.)	<u> </u>	 										
Other (spec.)		 		· · · · · ·								
Peripheral vessel		 	<u> </u>									
Other (spec.)			 									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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Table 4.3- 28 Diagnostic Ultrasound Indications for Use Form – WC40x/6-2 Transducer

System:	SonoSite	Maxx™	Series L	Itrasoun	d System							
Transducer:	WC40x/6	-2 MHz	Transduc	er	<u> </u>							
Intended Use:					uid flow ar	nalysis of the hum	an body as					
Clinical Application	Mode of Operation											
	В	М	PWD	CWD	Color Doppler	Combined	Other					
Ophthalmic				0110	Dopplei	(Spec.)	(Spec.)					
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Abdominal	N.	N	N		N	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Neuro.)	ļ						· · · · · · · · · · · · · · · · · · ·					
Laparoscopic	 											
Pediatric Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	N.	N	N		N	B+M; B+PWD; B+CD	Note 1					
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal					*							
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)					-							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Intra-luminal		<u> </u>										
Other (spec.)							· · · · · · · · · · · · · · · · · · ·					
Cardiac Adult												
Cardiac Pediatric												
Trans-esophageal (card.)	ļ											
Other (spec.)	ļ <u>.</u>											
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Other (spec.)							11010 1					

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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Table 4.3- 29 Diagnostic Ultrasound Indications for Use Form – WC60x/6-2 Transducer

System:	SonoSite	Maxx™	Series L	Itrasoun	d System	·						
Transducer:	WC60x/6	-2 MHz	Transduc	er	- Cystoin							
Intended Use:					uid flow ar	nalysis of the hum	an body as					
Clinical Application	Mode of Operation											
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)					
Ophthalmic					<u> </u>	(Opec.)	(Spec.)					
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Intra-operative (Neuro.)	-											
Laparoscopic		<u> </u>				-						
Pediatric	N_	N	N		N	B+M; B+PWD; B+CD	Note 1					
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal						-						
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Intra-luminal	ļ <u>.</u>											
Other (spec.)												
Cardiac Adult												
Cardiac Pediatric												
Trans-esophageal (card.)												
Other (spec.)												
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1					
Other (spec.) N= new indication: P= previously clea							11010 1					

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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Table 4.3- 30 Diagnostic Ultrasound Indications for Use Form – WL25x/12-5 Transducer

System:	SonoSite	Maxx™	Series L	Iltrasoun	d System						
Transducer:		WL25x/12-5 MHz Transducer									
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application	Mode of Operation										
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)				
Ophthalmic	N .	N	N		N	B+M; B+PWD; B+CD	Note 1				
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Intra-operative (Neuro.) Laparoscopic	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Pediatric	N	N N	N		N	B+M; B+PWD; B+CD	Note 1				
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Adult Cephalic		ļ									
Trans-rectal											
Trans-vaginal											
Trans-urethral		<u> </u>									
Trans-esoph. (non-Card.) Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Intra-luminal	 	 									
Other (spec.)	-		<u> </u>								
Cardiac Adult Cardiac Pediatric	 	 	ļ								
Trans-esophageal (card.)			 								
Other (spec.)	 	<u>-</u>	-								
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Other (spec.) N= new indication: P= previously clear											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined 8 and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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Table 4.3- 31 Diagnostic Ultrasound Indications for Use Form - WL40x/12-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System										
Transducer:	WL40x/12-5 MHz Transducer										
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application	Mode of Operation										
	В	м	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)				
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Abdominal	l N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Intra-operative (Neuro.)	N	N_	N		N	B+M; B+PWD; B+CD	Note 1				
Laparoscopic	<u> </u>		<u> </u>								
Pediatric	N_	N	N		N	B+M; B+PWD; B+CD	Note 1				
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Neonatal Cephalic	N_	N	N		N	B+M; B+PWD; B+CD	Note 1				
Adult Cephalic	ļ	ļ <u>.</u>									
Trans-rectal	 	 									
Trans-vaginal	 	 									
Trans-urethral Trans-esoph. (non-Card.)	-		ļ								
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Intra-luminal											
Other (spec.)											
Cardiac Adult	ļ										
Cardiac Pediatric		<u> </u>									
Trans-esophageal (card.)	 	 	<u> </u>								
Other (spec.)	 										
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1				
Other (spec.)	<u> </u>										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined 8 and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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Table 4.3- 32 Diagnostic Ultrasound Indications for Use Form – WMC15x/12-4 Transducer

System:	SonoSite Maxx™ Series Ultrasound System										
Transducer:	WMC15x/12-4 MHz Transducer										
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body a follows:										
Clinical Application	Mode of Operation										
	_D		514.55		Color	Combined	Other				
	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)				
Ophthaimic	N	N	N	N	Ņ	B+M; B+PWD; B+CD; B+CWD	Note 1				
Fetal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Intra-operative (Abdominal organs and vascular)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Intra-operative (Neuro.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Laparoscopic						20,2000					
Pediatric	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Small Organ (breast, thyroid, testicles, prostate)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Neonatal Cephalic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Adult Cephalic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Trans-rectal						5.0D, B.0VVD					
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Convent.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Musculo-skel. (Superfic.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Intra-luminal	ļ. <u></u>										
Other (spec.)	 	.									
Cardiac Adult		<u> </u>									
Cardiac Pediatric	ļ	 	. <u> </u>								
Trans-esophageal (card.) Other (spec.)	 	 									
Outer (spec.)	 										
Peripheral vessel	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Other (spec.)		1									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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Table 4.3- 33 Diagnostic Ultrasound Indications for Use Form – WMC20x/12-4 Transducer

System:	SonoSite Maxx™ Series Ultrasound System										
Transducer:	WMC20x/12-4 MHz Transducer										
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body a									
Clinical Application	Mode of Operation										
	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)				
Ophthalmic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Fetal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Abdominal	N_	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Intra-operative (Abdominal organs and vascular)	N	N_	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Intra-operative (Neuro.)	N	N_N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Laparoscopic			<u> </u>								
Pediatric Small Organ (breast, thyroid,	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
testicles, prostate)	N_	N_	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Neonatal Cephalic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Adult Cephalic Trans-rectal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Trans-vaginal	 		<u> </u>								
Trans-urethral		+									
Trans-esoph. (non-Card.)		<u> </u>									
Musculo-skel. (Convent.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Musculo-skel. (Superfic.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Intra-luminal Other (spec.)		 									
Cardiac Adult	 	 									
Cardiac Pediatric		 									
Trans-esophageal (card.)		1									
Other (spec.)		 					<u> </u>				
Peripheral vessel	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1				
Other (spec.)					- ,1	D.OD, BTOVVD					

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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Table 4.3- 34 Diagnostic Ultrasound Indications for Use Form – WTVx/9-3 Transducer

System:	SonoSite Maxx™ Series Ultrasound System									
Transducer:	WTVx/9-3 MHz Transducer									
Intended Use:						or fluid flow analysis o	f the			
	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application										
101000000000000000000000000000000000000	Mode of Operation									
	В	М	PWD	CWD	Color	Combined	Other			
Ophthalmic	-	1 1 1	1 1 1 1 1	CVVD	Doppler	(Spec.)	(Spec.			
Fetal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1			
Abdominal	T	···	''	''		B+CVVD				
Intra-operative (Abdominal organs and vascular)							<u> </u>			
Intra-operative (Neuro.)		<u> </u>								
Laparoscopic							<u> </u>			
Pediatric										
Small Organ (breast, thyroid, testicles, prostate)		_					<u> </u>			
Neonatal Cephalic	_									
Adult Cephalic	_									
Trans-rectal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1			
Trans-vaginal	N	Z	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1			
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skel. (Convent.)										
Musculo-skel. (Superfic.)										
Intra-luminal										
Other (spec.)										
Cardiac Adult										
Cardiac Pediatric					· · · · · ·		· · · · · · · · · · · · · · · · · · ·			
Trans-esophageal (card.)										
Other (spec.)										
Peripheral vessel										
Other (spec.) N= new indication; P= previously cleared by FDA: E= ad										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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